MAR - 2 2009

K073596

510(k) SUMMARY

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information: ClearStream Technologies Ltd, Moyne Upper, Enniscorthy, Co Wexford, Ireland. Phone: 00 353 53 9237111 Fax: 00 353 53 9237100

Date Summary Prepared: March 19, 2008

Contact Person: Fiona Ní Mhullain

Device Name: Trade Name(s): ReeKross™, ReeKross™14 and ReeKross™18 over the wire Peripheral Transluminal Angioplasty (PTA) Catheters

Classification Name: Percutaneous Catheter

Classification Regulation: 21 CFR 870.1250

Panel: Cardiovascular

Product Code: LIT

Predicate Device Information:

Device Name: Savvy Long

Manufacturer: ClearStream Technologies Ltd

Reference: K072947

Device Description:

The ReeKross family of over the wire PTA catheters are a balloon dilation catheter for angioplasty. They consist of a stainless steel guidewire shaft that extends from the proximal hub to the distal tip of the catheter. This stainless steel shaft has a spiral cut positioned at its distal end. The spiral cut is laser cut and passivated following completion. A polymer bodybond material is used to seal the spiral cut and ensure that the contrast solution remains in the inflation lumen only and does not leak into the guidewire lumen. This bodybond material is fused onto the outside diameter of the stainless steel shaft. A copolymer inflation lumen extends from the proximal hub of the catheter to the proximal shoulder of the balloon. The lumen of the shaft is used for the purpose of inflating and deflating the balloon. This outer is thermally fused to the balloon's proximal shoulder.

The balloon material is a Nylon/Pebax blend. Low Profile Platinum Radiopaque bands are used to locate the balloon under fluoroscopy. These bands are swaged onto the bodybond material sealing the spiral cut section of the guidewire lumen.

Intended Use:

Balloon dilatation of the femoral, popliteal and infra popliteal arteries. These catheters are not designed to be used in the coronary arteries.

Comparison to Predicate Device:

This device is equivalent to the predicate device in intended use, design characteristics and general physical characteristics.

Testing and Conclusion:

Performance testing and compliance with recognized standards have established substantial equivalence with regard to safety and effectiveness.

(Please include 510(k) number here: K083596)

HFZ #	Last Name	Date	HFZ #	Last Name	Date	HFZ #	Last Name	Date
450	Courtney	2/27/09						
450	Carnagl	2/27/09						
Z-450	[illegible]	2/27/09						

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-450 Division
D.O.

Prepared by:TDCourtney:myb:02/27/09

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ClearStream Technologies, Inc.
c/o Mr. Robert A. van Boxtel
KEMA Quality B.V.
Utrechtseweg 310
Arnhem
Netherlands NL-6812 AR

MAR - 2 2009

Re: K083596
Trade Name: Reekross OTW PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 19, 2009
Received: February 20, 2009

Dear Mr. van Boxtel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vickney

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083596

Device Name: ClearStream Technologies PTA Catheters

Indications for Use:

Balloon dilatation of the femoral, popliteal and infra-popliteal arteries. These catheters are not designed to be used in the coronary arteries.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083596

CONFIDENTIAL